Tab 21 PREMARKET NOTIFICATION 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:

Manufacturer:

SonoScape Company Limited

Address: 4/F., Yizhe Building, Yuquan Road, Nanshan, Shenzhen 518051,

P.R.China

Tel: (86) 755-26722890

Fax: (86) 755-26722850

Contact Person: Zhiqiang Chen

Date Prepared: Feb 12, 2011

Name of the device:

* Trade/Proprietary Name:

S20 Digital Color Doppler Ultrasound System

* Common Name: Diagnostic Ultrasound System and Transducers

* Classification:

Regulatory Class: II

Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

Legally Marketed Predicate Device:

Premarket Notification 510(k) Summary

SonoScape S8 Diagnostic Ultrasound System and Transducers - K092922

Device Description:

The SonoScape S20 ultrasound system is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The all digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in-depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features.

This SonoScape system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound data and display the image in B-Mode (including Tissue Harmonic Image), M-Mode,TDI, Color-Flow Doppler, Pulsed Doppler and Power Doppler, or a combination of these modes, 3D/4D.

Intended Use:

The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

Probe Information:

Tab 21.1 Probe information

No.	Probe	Туре	Frequency Range	Intended Use				
1	2P1	Phased Array	2.0-4.0 MHz	Abdomina				
		1	}	Neonatal Cephalic				
				Adult Cephalic				
	ļ			Cardiac Adult				
				Cardiac Pediatric				
2	5P1	Phased Array	3.0-7.0 MHz	Pediatric				
				Neonatal Cephalic				
				Cardiac Pediatric				
3	6V1	Micro-curved	4.0-8.0 MHz	Trans-rectal				
		Array		Trans-vaginal				
4	6V3	Micro-curved	5.0-9.0 MHz	Trans-rectal				
		Array		Trans-vaginal				
5	EC9-5	Micro-curved	5.0-9.0 MHz	Trans-rectal				
		Array		Trans-vaginal				
6	C611	Micro-curved	4.0-8.0 MHz	Abdominal				
	•	Array		Pediatric				
j			· ·	Neonatal Cephalic				
<u> </u>				Cardiac Pediatric				
7	C344	Curved Array	2.0-5.0 MHz	Fetal / Abdominal/ Ob/GYN				
8	C362	Curved Array	2.0-6.0 MHz	Fetal / Abdominal/ Ob/GYN				
9	VC6-2	Curved Array	2.0-6.0 MHz	Fetal / Abdominal/ Ob/GYN				
10	L741	Linear Array	5.0-10.0 MHz	Small Organ (reast, thyroid,				
		·		testes)				
				Musculo-skeletal (Conventional)				
<u> </u>				Peripheral vessel				
11	L742	Linear Array	5.0-12.0 MHz	Small Organ (reast, thyroid,				
				testes)				
				Musculo-skeletal (Conventional)				
				Musculo-skeletal (Superficial)				
				Peripheral vessel				
12	L743	Linear Array	5.0-10.0 MHz	Small Organ (reast, thyroid,				
				testes)				
				Musculo-skeletal (Conventional)				
				Musculo-skeletal (Superficial)				
				Peripheral vessel				

Safety Considerations:

The S20 Diagnostic Ultrasound System with added transducer incorporates the same fundamental technology as the predicate device. The device has been tested as Track 3 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems Premarket Notification 510(k) Summary 21-3

and Transducers" issued September 9, 2008. The acoustic output is measured and calculated per NEMA UD 2: 2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment and NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment. The device conforms to applicable medical device safety standards, such as IEC 60601-1, IEC 60601-1,

Testing:

Laboratory testing was conducted to verify that the S20 Digital Color Doppler Ultrasound System with added transducer met all design specification and was substantially equivalent to the currently marketed Predicate Device as above. The device has been found to conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility. Acoustic output is measured and calculated according to "Acoustic Output Measuring Standard for Diagnostic Ultrasound Equipment".

Tab 21.2 Applicable Safety Standards

Standards No.	Standards Title	Version	Date
IEC 60601-1	IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.	1988	10/31/2005
IEC 60601-1-2	IEC 60601-1-2, (Second Edition, 2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility Requirements and Tests.	2007	07/31/2008
	IEC 60601-2-37 (2004) (2005) Amendment 2, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.		09/08/2009

	NEMA UD 2-2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Version 3.		09/08/2009
	ISO 10993-5:1999, Biological evaluation of medical devices Part 5: Tests for In Vitro cytotoxicity.	2009	09/12/2007
10993-10	ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity.		09/12/2007

Conclusion:

The conclusions drawn from testing of the S20 Diagnostic Ultrasound System with added transducer demonstrate that the device is as safe and effective as the legally marketed predicate devices.

L743 Linear Array L741 Linear Array L742 Linear Array





Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

SonoScape Company Limited % Ms. Diana Hong General Manager Mid-Link Consulting Co., Ltd. P.O. Box 237-023 Shanghai, 200237 CHINA

MAY 1 6 2011

Re: K110510

Trade/Device Name: S20 Digital Doppler Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: February 18, 2011 Received: February 22, 2011

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the S20 Digital Doppler Ultrasound System, as described in your premarket notification:

Transducer Model Number

EC9-5 Micro-curved Array
C611 Micro-curved Array
C362 Curved Array
C344 Curved Array
VC6-2 Curved Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely Yours,

Mary S. Pastel, Sc.D.

Director

Division of Radiological Devices Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

Muhal D. Oku to a

Enclosure(s)

4.4 Tab 3 Indications For Use

510(k) Number:

Device Name: S20 Digital Doppler Ultrasound System

Indications for Use:

The SonoScape S20 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

Prescription Use	X
(Part 21 CFR 801	Subpart D)

AND/OR

Over-The-Counter Use _____(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) Number 61/65/()

System:

Sonoscape S20

Diagnostic Ultrasound Pulsed Echo System

Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clin	ical Application					Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppier	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging&	Fetal	N	N	N		N	N	Note 1	Notes 2,4,5
Other	Abdominal	N	N	N		N	N	Note 1	Notes 2,4,5
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	Ν	N		N	N	Note 1	Notes 2,4
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,4,6
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-urethral		Ì						
	Trans-esoph.(non-Card)			···					
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2,4,5
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Intravascular(Cardiac)					<u> </u>			
	Trans-esoph.(Cardiac)]			
	Intra-cardiac								
	Other (specify)				l				
Peripheral	Peripheral vessel	N	Ν	N		N	N	Note 1	Notes 2,4
Vessel	Other (specify)		Ī						

	Intra-cardiac	ļ							
	Other (specify)								
Peripheral	Peripheral vessel	N	Ν	N		Z	N	Note 1	Notes 2,4
Vessel	Other (specify)								
Note 2: Tissue I Note 3: TDI	; P = p ombined includes: B/M; ler/PWD Harmonic Imaging. The Note 4: 3D organ: breast, thyroid, tes	B/PWD feature	; B/I does	-	color M ; l			= added under th oppler/PWD; E	
Prescription Use (Part 21 CFR 80 (PLEAS		OW TH	IS L	AND/O		ON ANOTH	(21 (Counter Use _ CFR 807 Subpa	
	Concurrence of CDRH	I, Office	of I	ı Vitro D	iagnostic	Devices (OIV	/D)		

Indications For Use

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K_K_110510

Transducer: 2P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cli	nical Application		Mode of Operation								
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify		
Ophthalmic	Ophthalmic										
Fetal Imaging&	Fetal					_					
Other	Abdominal	N	N	N	Ĭ	N	N	Note 1	Notes 2,4		
	Intra-operative Specify										
	Intra-operative Neuro										
	Laparoscopic										
	Pediatric										
	Small Organ (specify)										
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4		
	Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4		
	Trans-rectal										
	Trans-vaginal								-		
	Trans-urethral										
	Trans-esoph.(non-Card)										
	Musculo-skeletal (Conventional)										
	Musculo-skeletal (Superficial)										
	Intravascular	1					 				
	Other (Ob/GYN)										
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	Notes 2,3,4		
	Cardiac Pediatric	N	Ν	N	N	N	N	Note 1	Notes 2,3,4		
	Intravascular(Cardiac)										
	Trans-esoph.(Cardiac)										
	Intra-cardiac										
	Other (specify)										
Peripheral	Peripheral vessel										
Vessel	Other (specify)										

vessei	Other (specify)					
N = new indication;		P = previously cleared by FDA;		E =	added under this	appendix
		B/M; B/PWD; B/THI; M/Col	or M; B/Color Dopp	ler; B/Color Do	ppler/PWD; B/	Power
	er/PWD					
Note 2: Tissue F	larmonic Imaging.	The feature does not use con	ntrast agents			
Note 3: TDI	Note 4: 3D	Note 5: 4D				
Note 6: Small O	rgan: breast, thyroi	id, testes				
Prescription Use (Part 21 CFR 80		AND/OR	i.		Counter Use FR 807 Subpart	:C)
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	Concurrence of C	CDRH, Office of In Vitro Dia	gnostic Devices (OIV	'D)	,	

Indications For Use

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 6116510

Transducer: 5P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cli	inical Application		Mode of Operation								
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify		
Ophthalmic	Ophthalmic										
Fetal Imaging&	Fetal										
Other	Abdominal										
	Intra-operative Specify										
	Intra-operative Neuro										
	Laparoscopic										
	Pediatric	N	Ν	N		N	N	Note 1	Notes 2,4		
	Small Organ (specify)										
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4		
	Adult Cephalic										
	Trans-rectal								1		
	Trans-vaginal					l					
	Trans-urethral			-	·-						
	Trans-esoph.(non-Card)										
	Musculo-skeletal (Conventional)										
	Musculo-skeletai (Superficial)										
	Intravascular										
	Other (Ob/GYN)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3,4		
	Intravascular(Cardiac)				_						
	Trans-esoph.(Cardiac)										
	Intra-cardiac										
	Other (specify)										
Peripheral	Peripheral vessel							_	<u> </u>		
Vessel	Other (specify)										

Vessel	Other (specify)								
N = new indicati	on;	P = previo	usly clear	ed by FDA;			E	= added under this	appendix
	Combined includes: pler/PWD	B/M; B/P	WD; B/	гні; м/с	olor M ;	B/Color Dopp	oler; B/Color Do	oppler/PWD; B/	Power
Note 2: Tissue	Harmonic Imaging.	The fear	ture does	not use c	ontrast a	gents			
Note 3: TDI	Note 4: 3D			ote 5: 4D	,	-			
Note 6: Small	Organ: breast, thyro	id, testes							
	Jse XX 801 Subpart D)			AND/O	R			Counter Use FR 807 Subpart	
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Indications For Use

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

3-4

510K KUASIO

Transducer: 6VI Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cl	inical Application	_ _	Mode of Operation								
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify		
Ophthalmic	Ophthalmic	\neg			1						
Fetal Imaging&	Fetal										
Other	Abdominal					<u> </u>]				
	Intra-operative Specify							j			
	Intra-operative Neuro										
	Laparoscopic										
	Pediatric					İ					
	Small Organ (specify)			•		İ					
	Neonatal Cephalic					i					
	Adult Cephalic	_				i					
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4		
	Trans-vaginal	N	N	N	† 	N	N	Note 1	Notes 2,4		
	Trans-urethral	1									
	Trans-esoph.(non-Card)	_									
	Musculo-skeletal (Conventional)										
	Musculo-skeletal (Superficial)										
	Intravascular										
	Other (Ob/GYN)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intravascular(Cardiac)				Ì						
	Trans-esoph (Cardiac)	\neg			i						
	Intra-cardiac										
	Other (specify)										
Peripheral	Peripheral vessel										
Vessel	Other (specify)										

	Trans-esoph (Cardiac)			1					
	Intra-cardiac						ļ		
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Other (specify)								
N = new indication	on; P = pre	viously clea	red by FD	A;			E = added	under this	appendix
	Combined includes: B/M; B pler/PWD	/PWD; B	/THI; M/	Color M ;	B/Color Dop	opler; B/Colo	or Doppler/P	WD; B/I	Power
Note 2: Tissue	Harmonic Imaging. The fo	eature doc	s not use	contrast a	igents				
Note 3: TDI	Note 4: 3D	1	Note 5: 41	D					
Note 6: Small	Organ: breast, thyroid, teste	S							
Prescription U (Part 21 CFR	seX_ 801 Subpart D)		AND/	OR			The-Counter 21 CFR 807		<u>C)</u>
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Indications For Use

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K 15110510

Transducer: 6V3 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
	1			
	N	N	Note 1	Notes 2,4
	N	N	Note 1	Notes 2,4
			•	
			_	
Ĭ				
	B/Color Dop			
	contrast a		Color M : B/Color Doppler; B/Color Do	Color M; B/Color Doppler; B/Color Doppler/PWD; B/contrast agents

11010 2. 115540 1141	mome magnig.	catate dees not not contrast against	
Note 3: TDI	Note 4: 3D	Note 5: 4D	
Note 6: Small Org	an: breast, thyroid, teste	es	
Prescription Use _	X	AND/OR	Over-The-Counter Use
(Part 21 CFR 801			(21 CFR 807 Subpart C)
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Indications For Use

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

3-6

510K K110510

Transducer: EC9-5 Micro-curved Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	sical Application					Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	м	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging&	Fetal								
Other	Abdominal		l				<u> </u>	<u>.</u>	
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)				İ				
	Neonatal Cephalic								
	Adult Cephalic				1				
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-vaginal	l N	N	N		N	N	Note 1	Notes 2,4
	Trans-urethral	1	1	 					<u> </u>
	Trans-esoph.(non-Card)	+	 						
	Musculo-skeletal	+							
	(Conventional)								
	Musculo-skeletal		····			·			
	(Superficial)			l i					1
	Intravascular								
	Other (Ob/GYN)		Ĭ						
Cardiac	Cardiac Adult]			
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)				-				ļ
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Other (specify)		1						
	on; P = prev Combined includes: B/M; B/			d by FDA HI; M/C		B/Color Dop		= added under thi oppler/PWD; B	
	pler/PWD		3 .						
	Harmonic Imaging. The fe	ature				gents			
Note 3: TDI	Note 4: 3D		No	ote 5: 4D					
Note 6: Small	Organ: breast, thyroid, testes	8						•	

Doppler/PWD		
Note 2: Tissue Harmonic Imaging. The	e feature does not use contrast agents	
Note 3: TDI Note 4: 3D	Note 5: 4D	
Note 6: Small Organ: breast, thyroid, te	stes	•
Prescription UseX	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)
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Indications For Use

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Transducer: C611 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clini					Mode	of Operation			
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging&	Fetal								
Other	Abdominal	N	Z	N		N	N	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2,4
	Small Organ (specify)	1							
	Neonatal Cephalic	N	Ν	N	N	N	N	Note 1	Notes 2,3,4
	Adult Cephalic						ĺ		
	Trans-rectal					<u> </u>			
	Trans-vaginal					•			
	Trans-urethral								
	Trans-esoph.(non-Card)								-
	Musculo-skeletal (Conventional)								
	Musculo-skeletal	1	1		i				
	(Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult						l		
	Cardiac Pediatric	N	Ν	N	N	N	N	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph (Cardiac)					<u> </u>			
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel					i			
Vessel	Other (specify)								

N = new indication;	P	= previously cleared by FDA;	E = added under this appendix
Note 1: Other Con	bined includes: B/i	M; B/PWD; B/THI; M/Color M; B/Color	Doppler; B/Color Doppler/PWD; B/Power
Doppler/	PWD		
Note 2: Tissue Har	monic Imaging. T	he feature does not use contrast agents	
Note 3: TDI	Note 4: 3D	Note 5: 4D	
Note 6: Small Orga	an: breast, thyroid,	testes	
Prescription Use	X	AND/OR	Over-The-Counter Use
(Part 21 CFR 801	Subpart D)		(21 CFR 807 Subpart C)
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(Concurrence of CD	RH, Office of In Vitro Diagnostic Devices	s (OIVD)

Indications For Use

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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Transducer: C362 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cli	nical Application					Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	м	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal	N	Ν	N		N	N	Note 1	Notes 2,4
Other	Abdominal	N	Ν	N		N	N	Note1	Notes 2,4
	Intra-operative Specify				•				
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic	1			·				
	Adult Cephalic								
	Trans-rectal	 					<u> </u>		
	Trans-vaginal								
	Trans-urethral				-	<u> </u>	 		
	Trans-esoph.(non-Card)							1	
	Musculo-skeletal (Conventional)	1							
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N	•	N	N	Note1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)	1				<u> </u>		1	
	Trans-esoph.(Cardiac)	İ			-	1			
	Intra-cardiac	1							
	Other (specify)	1					1		
Peripheral	Peripheral vessel	1-	1		Ì	-			
Vessel	Other (specify)					1	1		

Chipholai	i onphoral record		1 1		1		1	į.
Vessel	Other (specify)							
N = new indication	on;	P = previous	ly cleared by FD	A;		Е	= added under thi	s appendix
	Combined includes	: B/M; B/PW	/D; B/THI; M	Color M	; B/Color Dopp	ler; B/Color De	oppler/PWD; B	Power
Dop	pler/PWD						_	
Note 2: Tissue	Harmonic Imaging	. The featu	re does not use	contrast	agents			
Note 3: TDI	Note 4: 3D		Note 5: 4	D				
Note 6: Small	Organ: breast, thyro	oid, testes						
Prescription U	/seX_ 801 Subpart D)		AND	/OR			Counter Use FR 807 Subpar	
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	Concurrence of	CDRH, Offi	ce of In Vitro	Diagnosti	c Devices (OIV	(D)	· · · · · · · · · · · · · · · · · · ·	

Indications For Use

(Division Sign-Orf)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Transducer: C344 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinic	cal Application					Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging&	Fetal	N	Ν	N		N	N	Note 1	Notes 2, 4
Other	Abdominal	N	И	N		N	N	Note 1	Notes 2, 4
	Intra-operative Specify								
	Intra-operative Neuro		1						
	Laparoscopic								
	Pediatric								<u> </u>
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal						1		
	Trans-urethral							•	
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Muscuło-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2, 4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								ļ
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Other (specify)	乚	<u> </u>			L	<u> </u>	<u> </u>	

1	intra-cardiac		i L.			i				
	Other (specify)					·				
Peripheral	Peripheral vessel								1	
Vessel	Other (specify)									
N = new indication;	P	= previously	leared	by FDA;				E = added (under this a	ppendix
Note 1: Other Cor Doppler	nbined includes: Bar PWD	M; B/PWD	B/TI	II; M/C	olor M ;	B/Color Do	ppler; B/Col	or Doppler/P	WD; B/P	ower
Note 2: Tissue Ha	rmonic Imaging.	The feature	loes n	ot use c	ontrast a	gents				
Note 3: TDI	Note 4: 3D		Not	e 5: 4D						
Note 6: Small Org	gan: breast, thyroid,	testes								
Prescription Use (Part 21 CFR 801				AND/O	R		-	The-Counter (21 CFR 807		Z)
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Indications For Use

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Transducer: VC6-2 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clini	cal Application					Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	M	PWD	CMD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal	N	N	Z		N	N	Note 1	Notes 2,4,5
Other	Abdominal	N	Z	N		N	N	Note 1	Notes 2,4,5
	Intra-operative Specify								
	Intra-operativé Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic			-		ĺ			
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph (non-Card)	†				 -			
•	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	Ν	N		N	N	Note 1	Notes 2,4,5
Cardiac	Cardiac Adult	l							
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Other (specify)								-

	i intravascaiai (Garaiae)	1 1 1				[
	Trans-esoph.(Cardiac)				,					
	Intra-cardiac									
	Other (specify)									
Peripheral	Peripheral vessel					1				
Vessel	Other (specify)								•	
Dopple	mbined includes: B/M; B/I	,	HI; M/Cole	·	,	pler; B/C		dded under th bler/PWD; B		
Note 3: TDI			te 5: 4D	masi ag	ZIII.3					
	gan: breast, thyroid, testes	NO	le 3. 4D							
Prescription Use (Part 21 CFR 801			AND/OR			Over-The-Counter Use(21 CFR 807 Subpart C)				
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Indications For Use

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

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Transducer: L743 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation										
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CMD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify				
Ophthalmic	Ophthalmic												
Fetal Imaging&	Fetal												
Other	Abdominal												
	Intra-operative Specify												
	Intra-operative Neuro												
	Laparoscopic					T							
	Pediatric												
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2, 4				
	Neonatal Cephalic												
	Adult Cephalic				· · · · ·		1						
	Trans-rectal												
	Trans-vaginal			·									
	Trans-urethral					·							
	Trans-esoph.(non-Card)								 				
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2, 4				
	Musculo-skeletal (Superficial)	N	N	Ν		N	N	Note 1	Notes 2, 4				
	Intravascular							·					
	Other (Ob/GYN)												
Cardiac	Cardiac Adult												
	Cardiac Pediatric												
	Intravascular(Cardiac)												
	Trans-esoph.(Cardiac)		1			İ							
	Intra-cardiac							i	 				
	Other (specify)					i		j	1				
Peripheral	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2, 4				
Vessel	Other (specify)		-										

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Vessel	Other (specify)		} "					`	
N = new indication	P = pre	riously	cleare	d by FD	۸;	· · · · · · · · · · · · · · · · · · ·	•	E = added under t	his appendix
Note 1: Other C	ombined includes: B/M; B	/PWD	; B/1	HI; M/	Color M	; B/Color	Doppler; B/Col	ог Doppler/PWD; I	B/Power
Doppl	er/PWD								
Note 2: Tissue F	larmonic Imaging. The fe	ature	does	not use	contrast	agents			
Note 3: TDI	Note 4: 3D		No	ote 5: 41)	_			
Note 6: Small O	rgan: breast, thyroid, teste	3							
Prescription Use	×			AND/	OR		Over-	The-Counter Use	
(Part 21 CFR 80							-	(21 CFR 807 Subpa	art C)
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Indications For Use

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Division of Radiological Devices

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Office of In Vitro Diagnostic Davice Evaluation and Safety

Transducer: L741 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	cal Application	Mode of Operation									
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify		
<u>Ophthalmic</u>	Ophthalmic	<u>.</u>									
Fetal Imaging&	Fetal .										
Other	Abdominal	ļ									
	Intra-operative Specify		igsquare						_		
	Intra-operative Neuro										
	Laparoscopic										
	Pediatric										
	Small Organ (specify)	N	Ν	N		N	N	Note 1	Notes 2, 4		
	Neonatal Cephalic]							,		
	Adult Cephalic	1									
	Trans-rectal		1				-				
	Trans-vaginal	 									
	Trans-urethral	 									
	Trans-esoph.(non-Card)								 		
	Musculo-skeletal	N	N	N		N	N	Note 1	Notes 2, 4		
	(Conventional)	'`	'	11		14	in .	Note	110162 2, 4		
	Musculo-skeletal	\vdash									
	(Superficial)	1									
	Intravascular	1									
	Other (Ob/GYN)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric	\vdash									
	Intravascular(Cardiac)	t	H								
	Trans-esoph.(Cardiac)	 					-	<u> </u>			
	Intra-cardiac	1				· · · · · · · · · · · · · · · · · · ·					
	Other (specify)	 				-					
Peripheral	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2, 4		
Vessel	Other (specify)							11.51.0	110100 2, 1		
Dopple Note 2: Tissue H Note 3: TDI	P = previor prombined includes: B/M; B/P er/PWD armonic Imaging. The feat Note 4: 3D gan; breast, thyroid, testes	WD;	B/F loes 1	HI; M/C	olor M ; l		E: oler; B/Color Do	= added under this oppler/PWD; B/	appendix Power		

renpileiai	r cripiteral vesser	1 14	1.4	114		11/4	l IN	Note 1	Notes 2,
Vessel	Other (specify)								
N = new indication;	P = pr	eviously o	leare	d by I	DA;		•	E = added under t	his appendix
Note 1: Other Co	mbined includes: B/M; I	3/PWD	B/1	HI; [и/Color I	M; B/Color I	Doppler; B/Col		
Dopple	er/PWD							11	
Note 2: Tissue H	armonic Imaging. The	eature o	loes	not u	ise contra	st agents			
Note 3: TDI	Note 4: 3D			ote 5:		C			
Note 6: Small Or	gan: breast, thyroid, test	es							
Prescription Use	Х			ΑN	D/OR		Over-	The-Counter Use	
(Part 21 CFR 80)					2,010			21 CFR 807 Subp	art C)
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Indications For Use

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Transducer: L742 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	nical Application		Mode of Operation										
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify				
Ophthalmic	Ophthalmic					·-	<u> </u>						
Fetal Imaging&	Fetal						ļ						
Other	Abdominal												
	Intra-operative Specify			_									
	Intra-operative Neuro												
	Laparoscopic												
	Pediatric			<u> </u>		_							
	Small Organ (specify)	N	7	N		N	N	Note 1	Notes 2, 4				
	Neonatal Cephalic												
	Adult Cephalic												
	Trans-rectal												
	Trans-vaginal						1						
	Trans-urethral					*****							
	Trans-esoph.(non-Card)												
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2, 4				
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2, 4				
	Intravascular						1		·				
_	Other (Ob/GYN)						1		_				
Cardiac	Cardiac Adult												
	Cardiac Pediatric								_				
	Intravascular(Cardiac)								i				
	Trans-esoph.(Cardiac)						Ì						
	Intra-cardiac												
	Other (specify)												
Peripheral	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2, 4				
Vessel	Other (specify)												

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	Other (specify)	j		1								
Peripheral	Peripheral vessel	N	Ν	N		N	N	Note 1	Notes			
Vessel	Other (specify)											
N = new indicatio	n; P = 1	reviously o	leare	d by FD	A;	<u>.</u>		E = added under	this appendi			
Note 1: Other (Combined includes: B/M	B/PWD	; B/I	'HI; M	Color M:	B/Color I	Doppler; B/Col					
	oler/PWD		•	•				,				
Note 2: Tissue	Harmonic Imaging. The	e feature	does	not use	contrast :	agents						
Note 3: TDI	Note 4: 3D			ote 5: 4								
Note 6: Small	Organ: breast, thyroid, te	stes										
	, ,											
Prescription Us	se X			AND	OR		Over-The-Counter Use					
(Part 21 CFR 8			(21 CFR 807 Subpart C)									
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Indications For Use

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